

REMARKS

Status of the Claims

Claims 2, 4-10, 24-43, 49-60, 63-66, 68-75 were pending. As shown above, claims 2 and 4 have been amended to return to previous claim language making it explicit that the Gag polypeptide encoded by the claimed polynucleotide elicits a Gag-specific immune response (*see, also*, Example 4). In addition, claims 2 and 4 have been amended to make explicit that the claimed polynucleotide sequences must exhibit at least 90% sequence identity to the full-length of SEQ ID NOs:3 or 4.

Thus, claims 2, 4-10, 24-43, 49-60, 63-66, 68-75 are pending as shown above.

Priority

The Office Action acknowledges that the claims have priority to the application filed September 1, 1999. (Office Action, page 2).

Rejections Withdrawn

Applicants note with appreciation that the obviousness-type double patenting rejection over application no. 09/967,464 have been withdrawn. (Office Action, page 3). In addition, the rejection under 35 U.S.C. § 112, 1st paragraph (enablement) has been withdrawn. (Office Action, page 7).

Obviousness-Type Double Patenting

Claims 2, 4, 41, 68, 69 and 74 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 6,602,705. (Office Action, page 3). Claims 7-10, 24-40 and 71-73 were also rejected as allegedly obvious over claims 4, 11, 12, and 14-30 of U.S. Patent No. 6,602,705. (Office Action, page 4).

In addition, claims 2, 4, 5, 7, 41, 68 and 70 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 7,211,659. (Office Action, page 4). Claims 49, 50, 51, 52, 54, 55, 56, 67 and 58 were

rejected under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claims 35, 36, 40, 41, 43, 37, 38, 39, 44 and 45 of U.S. Patent No. 7,211,659. (Office Action, page 5).

Applicants submit the appropriate terminal disclaimer herewith, thereby obviating these rejections.

35 U.S.C. § 112, 1st paragraph, written description

The rejection of claims 2, 4, 7-10, 24-43 and 49-60 under 35 U.S.C. § 112, 1st paragraph as allegedly not adequately described by the as-filed specification was maintained. (Office Action, pages 6-7). In particular, it was maintained that the claims encompass polynucleotides that encode Gag proteins that elicit non-specific immune responses and that “the specification does not disclose a correlation between the structure of the polynucleotides and the desired biological activity.” (Office Action, page 6 and page 7, 3rd full paragraph).

The pending claims are drawn to polynucleotides that encode Gag polypeptides and further specify that the Gag polypeptides elicit a Gag-specific immune response. Thus, the claims do not encompass polynucleotides that encode polypeptides that elicit a non-specific immune response.

Moreover, Applicants strongly traverse the assertion that the “specification” does not disclose a correlation between the structure of the polynucleotides and the desired biological activity. For the reasons detailed extensively throughout the lengthy prosecution of this application, the as-filed specification more than adequately describes how the polynucleotides as claimed encode Gag polypeptides that generate a Gag-specific immune response. Indeed, working examples (see, Example 4) showing how SEQ ID NOs:3 and 4 encode immunogenic HIV Gag polypeptides and elicit Gag-specific immune responses are provided. Thus, as-filed specification fully describes polynucleotides encoding polypeptides with the biological activity recited in the pending claims.

Furthermore, while Applicants completely agree that the claims are drawn to polynucleotides, the Office’s previous rejections have been based on the allegation that the Gag polypeptides encoded by the claimed polynucleotides have many diverse functions that were not necessarily present in the encoded polypeptides. (Office Action, page 7, 1st full paragraph).

Accordingly, Applicants have repeatedly noted that the claims are directed only to polynucleotides encoding Gag-specific immunogenic polypeptides and, as such, other functions of Gag polypeptides are not relevant.

In sum, the skilled artisan, having followed the teaching of the specification, would have no doubts that Applicants were in possession of the claimed subject matter. Accordingly, for all the reasons of record and those set forth herein, the as-filed specification more than satisfies the written description requirement of 35 U.S.C. § 112, 1st paragraph and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 102(b)

Claims 2, 4, 24, 25, 27, 39, 40 and 41 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schwartz et al. (1992) *J. Virol.* 66:7176-7128 (hereinafter “Schwartz”). (Office Action, pages 8-9). Schwartz was alleged to teach sequences of approximately 20 nucleotides within GenBank Accession No. L04602 that exhibit 90% sequence identity to fragments of the same length within SEQ ID NOs:3 and 4. (Office Action, page 9).

The pending claims are directed to polynucleotides having at least 90% sequence identity to full-length SEQ ID NO:3 or SEQ ID NO:4. As shown in the attached alignments, GenBank Accession No. L04602 as disclosed in Schwartz exhibits only 67% identity to full length SEQ ID NO:3 and 62% identity to full length SEQ ID NO:4.

Thus, Schwartz does not describe or demonstrate polynucleotides as claimed and withdrawal of the rejection is in order.

35 U.S.C. § 103(a)

Claims 7-10 and 24-29 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Schwartz in view of Persson et al. (1998) *Biologicals* 26:255-265. (Office Action, pages 9-12). Schwartz was cited as above and Persson was cited for teaching various modifications of an HIV expression construct encoding HIV protease and polymerase. *Id.* It was alleged that it would have been obvious to combine Schwartz’s Gag-encoding polynucleotides with Persson’s prot- and pol-encoding nucleotides and that such a combination would result in the claimed polynucleotides. *Id.*

For the reasons detailed above and has shown in the attached alignments, Schwartz in now way teaches or suggests polynucleotides having at least 90% identity to full length SEQ ID NO:3 or SEQ ID NO:4. As admitted by the Office, Persson also fails to teach such polynucleotides. Accordingly, there is no combination of these references that would result the claimed subject matter.

For at least these reasons, the rejection of claims 7-10 and 24-29 under 35 U.S.C. § 103(a) cannot be sustained.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is in condition for allowance. If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned.

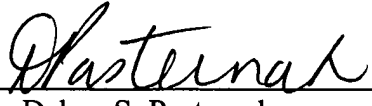
The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

Please direct all further written communications regarding this application to:

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Respectfully submitted,

Date: January 23, 2008

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ClustalW Results

Results of search

Number of sequences 2
Alignment score 1520
Sequence format Pearson
Sequence type nt
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Scores Table

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| SeqA Name | Len(nt) | SeqB Name | Len(nt) | Score |
|------------|---------|-----------------|---------|-------|
| 1 seqidno3 | 1479 | 2 genbankL04602 | 336 | 67 |

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Alignment

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CLUSTAL W (1.83) multiple sequence alignment

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seqidno3      ATGGGCGCCGCGCCAGCATCCTGCGCGGCGGCAAGCTGGACGCTGGGAGCGCATCCGC 60
genbankL04602 -----

seqidno3      CTGCGCCCCGGCGGCAAGAAGTGCTACATGATGAAGCACCTGGTGTGGGCCAGCGCGAG 120
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seqidno3      CTGGAGAAGTTGCGCCCTGAACCCCGGCGCTGTGGAGACCAGCGAGGGCTGCAAGCAGATC 180
genbankL04602 CTAGAAGATTGCGAGTTAATCTGCGCTGTAGAAACATCAGAAGGCTGTAGACAAATA 120
                * * * * *

seqidno3      ATCCGCCAGCTGCACCCCGCCTGCAGACCGGCAGCGAGGAGCTGAAGAGCCTGTTCAAC 240
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                * * * * *

seqidno3      ACCGTGGCCACCTGTACTGCGTGCACGAGAAGATCGAGGTCCGCGACACCAAGGAGGCC 300
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                * * * * *

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                * * * * *

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genbankL04602 -----

seqidno3      GAGAAGGCCTTCAGCCCCGAGGTGATCCCCATGTTACCGCCTGAGCGAGGGCGCCACC 534
genbankL04602 -----

seqidno3      CCCCAGGACCTGAACACGATGTTGAACACCGTGGGCGGCCACCAGGCCCATGCGAGATG 594
genbankL04602 -----

seqidno3      CTGAAGGACACCATCAACGAGGAGGCCGCGAGTGGGACCGGTGCACCCCGTCACGCC 654
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seqidno3      GGCCCCATCGCCCCCGGCCAGATGCGCGAGCCCCGCGGCAGCGACATCGCCGGCACCAAC 714
genbankL04602 -----
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seqidno3      AGCATCTGGACATCAAGCAGGGCCCCAAGGAGCCCTTCCGCGACTACGTGGACCGCTTC 894
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seqidno3      TTCAAGACCCCTGCGCGCCGAGCAGAGCACCCAGGAGGTGAAGAAGTGGATGACCGACACC 954
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genbankL04602 -----

seqidno3      ACCAGCCTGAAGAGCCTGTTCGGCAACGACCCCTGAGCCAGTAA 1479
genbankL04602 -----
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(seqidno3:0.16220,genbankL04602:0.16220);

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seqidno3
genbankL04602

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ClustalW Results

Results of search

| | |
|---------------------|---|
| Number of sequences | 2 |
| Alignment score | 1790 |
| Sequence format | Pearson |
| Sequence type | nt |
| ClustalW version | 1.83 |
| JalView | |
| Output file | clustalw-20071114-23101942.output |
| Alignment file | clustalw-20071114-23101942.aln |
| Guide tree file | clustalw-20071114-23101942.dnd |
| Your Input file | clustalw-20071114-23101942.input |

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Scores Table

| SeqA Name | Len(nt) | SeqB Name | Len(nt) | Score |
|------------|---------|-----------------|---------|-------|
| 1 seqidno4 | 1509 | 2 genbankL04602 | 396 | 62 |

PLEASE NOTE: Some scores may be missing from the above table if the alignment was done using multiple CPU mode. Please check the output.

Alignment

CLUSTAL W (1.83) multiple sequence alignment

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seqidno4      ATGGGCGCCGCGCCAGCATCCTGCGGGGAGAGCTGGACAAGTGGGAGAAGATCCGC 60
genbankL04602 ATGGGTGCGAGAGCGTCAGTATTAAAGCGGGGAGAATTAGATCGATGGGAAAAAATTCGG 60
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seqidno4      CTGCGCCCGCGGCAAGAAGCACTACATGCTGAAGCACCTGGTGTGGGCCAGCCGCGAG 120
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*****

seqidno4      CTGAGGGGCTTCGCCCTGAACCCCGGCTGCTGGAGACCGCGAGGGCTGCAAGCAGATC 180
genbankL04602 CTAGAACGATTTCGCAGTTAATCCTGGCTGTTAGAAACATCAGAAGCTGTAGACAAATA 180
*****

seqidno4      ATGAAGCAGCTGCAGCCCGCCCTGCAGACCCGACCGAGGAGCTGCGCAGCCTGTACAAC 240
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*****

seqidno4      ACCGTGGCCACCCCTGTACTGCGTGACCGCGGCATCGAGGTCCGCGACCAAGGAGGCC 300
genbankL04602 ACAGTAGCAACCTCTATTGTGTGCACCGCGGATCGAGATCAAGGACACCAAGGAAGCT 300
*****

seqidno4      CTGGACAAGATCGAGGAGGAGCAGAACAAGTCCAGCAGAAGACCCAGCAGGCCAAGGAG 360
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*****

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genbankL04602 -----

seqidno4      AGCCAGTAA 1509
genbankL04602 -----
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Cladogram

seqidno4
genbankL04602

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